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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,696	12/27/2001	Masahiko Tamura	TAMURA=4A	9284

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,696	TAMURA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

eriod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

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1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

isposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4 and 15-21* is/are allowed.

6)☐ Claim(s) *5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

pplication Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

riority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

ttachment(s)

☐ Notice of References Cited (PTO-892)
☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 7/29/04 are acknowledged, entered and considered. In view of Applicant's request claims 1, 2, 4, 6, 8-12, 15 and 16 have been amended and claim 21 has been added. Claims 1-21 are now pending in the application. The rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 103(a) and 35 U.S.C. 112, first paragraph for claims 1-4, 15-20 and newly submitted claim 21 are withdrawn in view of Applicant's amendment and remarks filed 7/29/04. However, the rejection under 35 U.S.C. 112, first paragraph for claims 5-14 is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing blood platelet formation or count in a patient suffering from thrmbocytopenia by administering a parathyroid

hormone (PTH), wherein the PTH is PTH (1-84) and PTH (1-34) as currently claimed in claims 1-4 and 15-21, does not reasonably provide enablement for administering all other derivatives of PTH for increasing blood platelet formation or count in patients suffering from thrombocytopenia purpura (claim 5), suffering from selective suppression of megakaryocytes (claim 6), has been or is being treated with phenylbutazone, gold compounds, tolbutamide and chemotherapeutics (claim 7), suffering from a viral infection (claim 8), suffering from aplastic anemia (claim 9), suffering from osteomyelodysplasis syndrome (claim 10), suffering from leukemia (claim 11), suffering from multiple myeloma (claim 12) and the various derivatives of PTH having substitution in the manner claimed in claims 13 and 14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 7/29/04 have been fully considered but they are not persuasive. Applicant's arguments that the specification discloses from the results of Examples 1-4, PTH (1-84) and the PTH derivative PTH (1-34) actually have a platelet increasing action, based on these results, one skilled in the art may reasonable expect that such partial peptides and variants of PTH (1-84) and PTH (1-34) as the specification discloses, which were known at the time of the present application was filed, e.g., PTH (1-38), PTH (35-84), PTH (1-37, would also have a platelet increasing action. Applicant concludes by stating that the law is clear that what an Applicant states in his specification is to be accepted by the PTO in the absence of evidence or good reasoning to the contrary, and as such, the claims are fully enabled by the specification

as originally filed, and that the requirements of the first paragraph of 35 U.S.C. 112, have been met is not persuasive. Contrary to Applicant's arguments, as discussed in the previous Office action, the instant specification teaches only how to use PTH (1-84) and PTH (1-34) in a method for increasing blood platelet formation or count in a patient as disclosed in Figures 1-4 and Examples 1-4. Figures 1-4 show the platelet increasing action of PTH at various frequencies of administration time and dosages and Examples 1-4 demonstrate the preparation of drug solution to be administered thereof as disclosed in Figures 1-4, respectively. However, the scope of the instantly claimed invention are very broad and speculative in that the various PTHs and their derivatives and substitutions as claimed can represent virtually any parathyroid hormone, and as such, the scope of the claims are extremely broad and relate to a very large number of possible PTHs of which some of them are not functional. For support, see the reference of Meytes et al. (J. Clin. Invest., Vol. 67, pp. 1263-1269, 1995) which teaches the effect of PTH on erythropoiesis and particularly on page 1265 states that not all the "derivative" of PTH exhibit the desired biological activity. Further, there is no working examples or data or evidence which shows that the claimed PTHs and their derivatives and substitutions are useful as a pharmaceutical composition for the intended purposes of increasing blood platelet formulation or count in patients suffering from the various disease conditions and situations as recited in claims 6-12.

Therefore, there is no evidence in the instant specification to use or administer the pharmaceutical formulations in therapeutically effective amount as claimed, except for the mere recitation of protocols on pages 6-9 and 16-17 in the instant specification

disclosing the range of effective dosages of a pharmaceutical composition to be administered in various route for the intended purpose of increasing blood platelet formation in various disease conditions and situations as claimed in claims 6-12. Further, there are no sufficient data or evidence to substantiate such protocols of using pharmaceutical compositions of claims 13 and 14 in the manner claimed. Hence, the only support for the claimed method and using the compositions thereof in the specification is Applicant's supposition of the invention as recited in the protocols. Furthermore, Applicant's claims are directed to a very large number of PTH and their derivatives and substitutions by using specific therapeutically effective amount of pharmaceutical formulation thereof, and there is no objective factual evidence in the specification showing that blood platelet formation or count has increased using the specific therapeutically effective amount of pharmaceutical composition claimed. Thus, one of ordinary skill in the art cannot administer specific effective amount of the pharmaceutical composition in all situations claimed without appropriate testing.

Therefore, in view of the above and in view of Meytes et al. reference, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of pharmaceutical composition in all kinds possible PTH and their derivatives and substitutions are contemplated and are encompassed as well as a wide range of treating various disease situations. The results desired appear to be highly dependent on all variables, the relationship of which

is not clearly disclosed. Hence, one of ordinary skill in the art would not be able to identify all the pharmaceutical preparations with wide range of dosages (i.e., 1 μg to 1, 000 μg per kg body weight, which is 1,000 times) intended to be effective for the claimed purposes as encompassed in the claims would be effective and under what conditions. Thus, the claims are based on pure speculation that the method would be effective since Applicant has not established any *nexus* between an effective amount of the claimed PTH and its derivatives, substituents and their use in the manner claimed. Secondly, the Examiner has clearly shown in the previous Office Action mailed on 01/29/04 and as discussed above that without guidance through working example(s), one of ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970).

Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 62-73, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above.

Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claim for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claim, the claim is not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claim or amendment of the claim to what is supported by the enabling disclosure is again suggested.

ACTION IS FINAL

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

4. Claims 1-4 and 15-21 are allowed and claims 5-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohamed/AAM
October 15, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER